REMARKS

Reconsideration of the application is respectfully requested. Claim 24 has been canceled, without prejudice or disclaimer. Claim 23 has been amended for clarification. Claims 40-42 have been amended to replace the terms "intermediate term treatment," "short term treatment," and "long term treatment" with their respective treatment periods. Support for this amendment is found in the specification at, for example, page 6, lines 10-12.

No new matter has been added. Claims 23 and 25-51 are pending and at issue.

Claim Objections

The Examiner has objected to claim 23 as being a substantial duplicate of claim 24. This rejection is moot because claim 24 has been canceled.

Rejections Under 35 U.S.C. §112, Second Paragraph

Claims 40-42 have been rejected under 35 U.S.C. §112, second paragraph, as indefinite. The Examiner states that the claimed "intermediate," "short," and "long" term treatments do not place clear limits on these claims.

Each of these claim terms is expressly defined in the specification at page 6, lines 10-12. Nevertheless, in order to expedite prosecution, claims 40-42 have been amended to include the definitions of "intermediate," "short," and "long" term treatments, respectively. One of ordinary skill in the art would readily comprehend the full scope of claims 40-42 when read in view of the specification, including the length of the treatment periods expressly recited therein. Accordingly, Applicant respectfully requests that this rejection be withdrawn.

Rejections Under 35 U.S.C. §103

Claims 23-28 and 39-42 have been rejected under 35 U.S.C. §103 as obvious over WO 00/51590 ("Radulovacki") in view of U.S. Patent No. 5,929,065 ("Lancel"). Radulovacki is cited by

the Examiner as disclosing the use of GABA receptor agonists to treat central, obstructive, and mixed apneas. Lancel is cited by the Examiner as disclosing the daily administration of a hypnotically effective amount of gaboxadol to treat sleep disorders. From this, the Examiner concludes that it would have been obvious to administer daily gaboxadol to treat sleep apnea.

The rejection of claim 24 is moot because this claim has been canceled. Regarding claims 23, 25-28, and 39-42, the rejection is respectfully traversed, and reconsideration is requested.

Radulovacki discloses that GABA receptor agonists can be used to prevent or ameliorate breathing disorders, and lists sleep apnea as such a disorder. However, there is clinical data showing that not all GABA receptor agonists are suitable for treating sleep apnea. For example, Radulovacki identifies zolpidem as a suitable compound for use in its methods (*see* p. 8, line 7). Zolpidem (Ambien®) was approved by the FDA for the short-term treatment of a sleep disorder (namely, insomnia characterized by difficulties with sleep initiation) and is contraindicated for patients with sleep apnea. *See* Ambien® Label at pp. 2 and 5 (warning that Ambien® "should be used with caution in patients suffering with sleep apnea syndrome") (copy attached as Exhibit A). Similarly, Cirignotta et al., *Pharmacol Biochem Behav*, 29(4):807-09 (1988) (Abstract) (copy attached as Exhibit B) discloses the results of a controlled double blind cross-over trial that assessed the effects of a single dose of 20 mg zolpidem on nocturnal breathing in patients with mild forms of sleep apnea syndrome. The results indicated that, at this dose, "the drug does not overcome the existing contraindications to the use of hypnotics in this syndrome." In other words, Cirignotta teaches that hypnotics are generally contraindicated for the treatment of sleep apnea – a conclusion later confirmed by the FDA with respect to zolpidem. Thus, despite Radulovacki's teaching, not all of the GABA receptor agonists mentioned in this reference are effective for treating sleep apnea.

Furthermore, sleep disorders are different from breathing disorders. Accordingly, a GABA receptor agonist may be an effective treatment for a sleep disorder (e.g., insomnia), but not an effective treatment for a breathing disorder (e.g., sleep apnea). The two disorders are not so related as to allow one of ordinary skill in the art to reasonably predict whether any one particular GABA receptor agonist would be successful in treating both disorders. In particular, one of ordinary skill would not expect zolpidem to be successful in treating sleep apnea, which impacts any reasonable expectation regarding the use of gaboxadol for such treatment. That is, one of ordinary

skill in the art would not have reasonably expected gaboxadol to be successful in treating both types of disorders based on the disclosure in Radulovacki, which provides no information as to which GABA receptor agonists listed in this reference, if any, might be successful in both preventing or ameliorating breathing disorders and treating a sleep disorder. In fact, based on the Ambien® Label and especially the results of the study described by Cirignotta et al., one of ordinary skill in the art would have been discouraged from using a hypnotic compound, such as gaboxadol, in an effort to treat sleep apnea with any reasonable expectation of success.

Lancel discloses the use of gaboxadol as a hypnotic, and makes no mention of respiratory function or any impact that gaboxadol may have on sleep apnea or any other sleep disorder that is specifically breathing-related. Consequently, Lancel fails to cure the deficiencies of Radulovacki.

Therefore, claims 23, 25-28, and 39-42 are not obvious over Radulovacki and Lancel, and Applicant respectfully requests that this rejection be withdrawn.

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Claim 29 has been rejected under 35 U.S.C. §103 as obvious over Radulovacki in view of Lancel, and further in view of Vandeputte et al., Sleep Medicine 4:343-45 (2003) ("Vandeputte)" and Sanchez et al., Psychiatry and Clinical Neurosciences 55:641-46 (2001) ("Sanchez"). Vandeputte is cited by the Examiner as disclosing a link between sleep disorders and depression. Sanchez is cited by the Examiner as disclosing that an effective sleep apnea therapy also alleviates depression. According to the Examiner, it would have been obvious to provide daily administration of gaboxadol to treat a patient suffering from sleep apnea and depression at the same time.

The rejection is traversed, and reconsideration is respectfully requested.

Neither Vandeputte nor Sanchez discloses the use of gaboxadol to treat sleep apnea. Accordingly, like Lancel, Vandeputte and Sanchez also fail to cure the deficiencies of Radulovacki. Thus, claim 29 is not obvious over the cited references for the same reasons advanced above, and Applicant respectfully requests that this rejection be withdrawn.

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Claims 30-32 and 43 have been rejected under 35 U.S.C. §103 as obvious over Radulovacki in view of Lancel, and further in view of EP 0000338 ("EP '338") and WO 02/40009 ("Ebert"). EP '338 is cited by the Examiner as disclosing acid addition salt forms, and zwitterions of gaboxadol. Ebert is cited by the Examiner as disclosing zwitterions gaboxadol base and salts thereof. According to the Examiner, it would have been obvious to treat sleep apnea by daily administration of gaboxadol in the various forms called for in these claims.

The rejection is traversed, and reconsideration is respectfully requested.

Neither EP '338 nor Ebert discloses the use of gaboxadol to treat sleep apnea. Accordingly, like Lancel, EP '338 and Ebert also fail to cure the deficiencies of Radulovacki. Thus, claims 30-32 and 43 are not obvious over the cited references for the same reasons advanced above, and Applicant respectfully requests that this rejection be withdrawn.

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Claims 33-38 and 44-48 have been rejected under 35 U.S.C. §103 as obvious over Radulovacki in view of Lancel, and further in view of EP '338. Radulovacki is cited by the Examiner as disclosing oral gaboxadol. Lancel is cited by the Examiner as disclosing gaboxadol in an oral dose of 5-50 mg/day. EP '338 is cited by the Examiner as disclosing various gaboxadol dosage forms, including tablets and liquids. According to the Examiner, it would have been obvious to treat sleep apnea by daily administration of gaboxadol in the various forms and amounts called for in these claims, and that determining particular amounts that lead to particular sleep periods would have been routine.

The rejection is traversed, and reconsideration is respectfully requested.

EP '338 does not disclose the use of gaboxadol to treat sleep apnea. Accordingly, like Lancel, EP '338 also fails to cure the deficiencies of Radulovacki. Thus, claims 33-38 and 44-48 are not obvious over the cited references for the same reasons advanced above, and Applicant respectfully requests that this rejection be withdrawn.

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Claims 49-51 have been rejected under 35 U.S.C. §103 as obvious over Radulovacki in view of Lancel and EP '338, and further in view of Krogsgaard-Larsen, Neuropharmacology

23(7B):837-38 (1984) ("Krogsgaard-Larsen") and WO 01/22941 ("Elema"). Krogsgaard-Larsen is cited by the Examiner as disclosing the relatively short half-life of gaboxadol. Elema is cited by the Examiner as disclosing gaboxadol controlled release formulations wherein about 75% of the gaboxadol is released after 3 hours, and over 90% is released after 5 hours. According to the Examiner, it would have been obvious to treat sleep apnea by daily administration of controlled release gaboxadol having the dissolution profiles called for in these claims.

The rejection is traversed, and reconsideration is respectfully requested.

None of EP '338, Krogsgaard-Larsen, or Elema discloses the use of gaboxadol to treat sleep apnea. Accordingly, like Lancel, EP '338, Krogsgaard-Larsen, and Elema also fail to cure the deficiencies of Radulovacki. Thus, claims 49-51 are not obvious over the cited references for the same reasons advanced above, and Applicant respectfully requests that this rejection be withdrawn.

Conclusion

In view of the above amendments and remarks, it is respectfully requested that the application be reconsidered and that all pending claims be allowed and the case passed to issue.

If there are any other issues remaining, which the Examiner believes could be resolved through either a Supplemental Response or an Examiner's Amendment, the Examiner is respectfully requested to contact the undersigned at the telephone number indicated below.

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Respectfully submitted,

By Dianna Goldenson

Dianna Goldenson
Registration No.: 52,949
DARBY & DARBY P.C.
P.O. Box 770
Church Street Station
New York, New York 10008-0770
(212) 527-7700
(212) 527-7701 (Fax)
Attorneys/Agents For Applicant